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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,241	12/13/2001	Roland Horres	49276-262679	1968

7590

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EXAMINER

BARRETT, THOMAS C

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,241	HORRES ET AL.	
	Examiner	Art Unit	
	Thomas C. Barrett	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 30-49 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues that the "RCE Submission of June 2005 states "[t]he native heparin sulfate materials contains trace impurities that come from other constituents of the outer layer of a red blood cell and/or mesothelial cell.' Thus, the subject impurities are indeed expressly covered by the claim language..." The submission does not constitute part of the specification as originally filed and therefore trace impurities are not disclosed.

The examples cited do not expressly teach one skilled in the art how to isolate a "constituent" including impurities. The examples are directed to isolating **a** constituent, not multiple constituents, some of which the Applicant argues can include the subject impurities, which are argued to be essential to the claimed invention. If the impurities are essential elements of the invention, are they actually impurities or additional constituents? Impurities can be virtually anything and therefore the claims are still not enabled. Furthermore, the claims are directed towards a hemocompatible surface **consisting of a** constituent. The Applicant points out that the transitional phrase "consisting of" excludes materials other than those recited except for impurities ordinarily associated therewith. However, what are the impurities **ordinarily** associated with the constituents? In addition, the Applicant fails to specifically show adequate

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support within the specification as filed for a hemocompatible surface **consisting of a** constituent...

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-49 remain rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The Applicant's arguments of June 29, 2005 state that the differences between commercially available heparin sulfate and native heparin sulfate is their purities and distribution of molecular weights. The trace impurities of the native heparin sulfate are admitted by the Applicant and are not disclosed or claimed, but are implied to be essential to the invention when compared to the commercially available product. The Applicant excluded any additional **essential** constituents when the claims were amended to include the transitional phrase "consists of". Furthermore, the Applicant has failed to disclose which impurities or molecular weights are essential to the present invention or how they can be determined by one of ordinary skill without undue experimentation.

Claims 30-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 30, 32, 39, 41-42, 47 and 49 recite the limitation "consists of", which was not described in the specification as originally filed as discussed in the above response to arguments section.

Regarding the Applicant's arguments directed towards Baumann et al, the oligoamide spacer, bonded to e.g. silicon, constitutes a compound as claimed, and the ESHS is the constituent chemically immobilized thereon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30-36, 38-39, 41-47 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Baumann et al (Semin Thromb Hemost.). Baumann et al discloses a hemocompatible surface comprising heparan sulfate, a polysaccharide constituent of an outer layer of a blood cell firmly attached to a compound. The Baumann et al implant consists of the same materials claimed and is hemocompatible. The declaration of June 29, 2005 admits the hemocompatibility of the of endothelial cell surface heparan sulfate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 40 and 48 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (5,718,159) in view of Baumann et al. Thompson discloses a vascular graft comprising a high-molecular weight polymer (col. 7, lines 46-52) however Thompson fails to disclose the graft coated with heparan sulfate. Baumann et al teaches a hemocompatible surface comprising heparan sulfate. It would have been obvious to one of ordinary skill in the art to combine the teaching of a heparan sulfate coating, as taught by Baumann et al, to a vascular graft as per Thompson, the motivation to combine being the coatings of Baumann et al show no platelet adhesion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a long horizontal flourish extending to the right.

Thomas Barrett
Examiner
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